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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,490	03/12/2001	Linda Burkly	CIBT-P01-114	2374

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1649

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 03/22/06, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments and persuasive arguments and upon further consideration.

Maintained Rejections:

Claims 1, 2, 5, 6, 9, 10, 13-17, 21-25, 30, 32, 34, and new claims 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent No: 6639051, Wang-EA, in view of Ericson-J et al., Cell 87(661-673)1996 and U.S. Patent No: 4816567 as set forth previously.

Wang teaches methods comprising administering hedgehog agonists to promote epithelial cell growth, including hair growth, and also methods comprising administering hedgehog antagonists to inhibit epithelial cell growth, including cutaneous, keratinocyte, mucosal, hair follicle, hair growth (anagen phase), see lines 10-22 of col3, lines 39-55 of col 6, lines 24-28 of col 8, lines 17-28 of col 9, lines 5-14 of col 11, and topical administration see lines 65 col 11-bridging col 12.

Wang does not however specifically teach that the hedgehog antagonist be an anti-hedgehog antibody, nor that the anti-hedgehog antibody be 5E1 or a humanized antibody. However, the use of anti-hedgehog antibodies as hedgehog antagonists was widely appreciated at the time of the filing of the Wang parent application. For example, Ericson et al. use anti-

Art Unit: 1649

hedgehog antibody 5E1 as a hedgehog antagonist to block the generation of floor plate cells and motor neurons, see the second to the last paragraph of col 2 of page 661.

The claims also require that the anti-hedgehog antibodies be chimeric antibodies or humanized. Both Wang-EA, and Ericson-J et al. appear to be silent with respect to chimeric antibodies, however the optimization of in vivo use of antibodies by making them chimeric antibodies was well established at the time of filing the Wang parent application. U Patent No: 4816567 teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies and humanized are more preferred, see col 2, lines 40-65, col 5, lines 22-35, col 6, lines 48-68, and cols 15 and 16 D.6 and D.7.

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success use anti-hedgehog antibodies as antagonists when practicing the method of Wang, the motivation to do so is provided by both Wang, who teaches that any hedgehog therapeutic that inhibits the activity of wild type hedgehog should be used as a matter of ordinary optimization of operating parameters (col 7, lines 41-43), and by Ericson who teach that anti-hedgehog antibodies can inhibit the activity of wild type hedgehog (col 2 of page 661), and to further routinely optimize the operation parameters, use 5E1 anti-hedgehog antibody as taught by Ericson, or to make a chimeric, or CDR grafted antibodies or humanized antibodies according to U.S. Patent No: 4816567 when practicing the invention of Wang as modified by Ericson. The motivation to do so is provided by Patent No: 4816567 who teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies and

Art Unit: 1649

humanized are more preferred, see col 2, lines 40-65, col 5, lines 22-35, col 6, lines 48-68, and cols 15 and 16 D.6 and D.7.

Applicant argues that the claims have been amended to be directed to topical administration. This argument has been fully considered but not deemed persuasive. As set forth above, Wang also teach topical administration, see lines 65 col 11-bridging col 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



June 9, 2006



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER